

REMARKS

The claims have been amended in various respects. Claim 1 has been amended to incorporate features in its dependent claim 9, which is canceled. Claim 10 is amended to be more consistent with its amended base claim 1. Claim 12 has been rewritten in independent form. Independent claims 14 and 36 now positively claim the magnetic field previously recited in more functional terms.

Dependent claim 16 has been amended to clarify an important difference between the claimed subject matter and the prior art cited in the office action. Independent claim 36 has been amended to include a feature in its dependent claim 40, which is canceled. Dependent claim 37 is amended in a fashion similar to claim 16.

Claims 1-8, 10-14, 16, 36-39, and 41-46 remain in the application; claims 1, 12, 14 and 36 are independent. There are fewer total claims and fewer independent claims than were originally paid for when the present application was filed. Therefore, no fee is due for additional claims.

All of the claims were examined on the merits, and all were rejected under 35 U.S.C. § 103 as reciting subject matter that would have been obvious from U.S. Patent 4,338,937 to Lerman in view of newly cited U.S. Patent 3,893,651 to Uecker.

The applicant believes that all of the independent claims are patentable, and that many of the dependent claims are patentable in their own right. In the latter regard, only dependent claims 16 and 37 include new subject matter not explicitly considered before now. The applicant discusses further below why the changes to claims 16 and 37 are properly entered even though the pending office action is a final rejection. The applicant requests that the examiner consider all of the dependent claims on their individual merits.

PATENTABILITY OF CLAIMED INVENTION

Claims 1 and 12

As noted, both of these claims are based on prior claim 1, which recited a trocar assembly comprising (a) a trocar including an elongated, generally annular cannula for extending through a tissue boundary and having a trocar base and (b) a trocar cap for removable attachment to a proximal end of the trocar base. The trocar further included a annular disc magnet surrounding a trocar lumen and the trocar cap included a magnetic member comprising a second magnet or a non-magnetized magnetically permeable member for magnetically securing the cap to the trocar base.

Lerman discloses a continent ileostomy or colostomy having an insert 40 with a stem portion 42 and a rim portion 44 that forms a flange on the stem portion. Four small, discrete magnets 52 are spaced circumferentially around the rim portion 44, as seen in Fig. 2, which also shows a cooperating set of four discrete magnets 86 located on the underside of a stopper 80. The office action conceded that claim 1's magnet comprising an annular disc at a proximal end of the trocar base and surrounding the trocar lumen differ from Lerman's discrete magnets 52.

The office action says that "Uecker teaches that it is known in the surgical art to have magnet 38 comprises [sic] an annular disc and the trocar cap 24 having a lumen 32 and a funnel-shaped 30 [sic] disposed therein." To start with, Uecker has nothing to do with "the surgical art." Rather, it discloses a dry well that is used to insert an instrument probe into a vessel such as a nuclear reactor. Uecker, at col. 1, lines 5-18. The examiner has not even addressed the question of whether one of ordinary skill in the art would have considered Uecker to be instructive of anything relating to a trocar assembly that comprises a trocar

including an elongated, generally annular cannula "for extending through a tissue boundary," as recited in the applicant's claim 1 and 12.

To use Uecker in a rejection of the applicant's claims, the examiner first must establish that Uecker is analogous art under the prevailing test applied by the PTO Board of Patent Appeals and Interferences:

When combining references to show non-obviousness [*sic*] under § 103, the Examiner must satisfy a two-prong test for analogous art, as set forth by the Federal Circuit in *In re Kahn*, 441 F.3d 977 [Fed. Cir. 2006]:

The analogous-art test requires that the Board show that a reference is either [1] in the field of the applicant's endeavor or [2] is reasonably pertinent to the problem with which the inventor was concerned in order to rely on that reference as a basis for rejection. References are selected as being reasonably pertinent to the problem based on the judgment of a person having ordinary skill in the art.

Kahn, 441 F.3d at 986-87 (emphasis added) (internal citations omitted). *Ex parte Nowlin*, Appeal No. 2009-0846, March 16, 2009 (Bd. Pat. Apps. & Inter.; copy attached), at page 8.

Ex parte Hong, Appeal No. 2009-005841, September 30, 2009 (Bd. Pat. Apps. & Inter.; copy attached), elaborates on the examiner's burden to establish that a particular reference constitutes analogous art. In *Hong* the rejected claim was directed to "algae-resistant roofing granules" and the Greenberg reference disclosed a flea collar. The examiner contended that Greenberg was analogous art, but the Board reversed because the examiner had not "reasonably explained" how Greenberg's flea-collar teachings would have suggested modifying the roofing-granule reference. *Id.*, at page 11.

In the present case, the examiner has not even made a pass at explaining how the teachings of Uecker with respect to a dry well for a nuclear reactor would have suggested modifying Lerman's continent ileostomy or colostomy. The examiner's statement that "Uecker teaches that it is known in the surgical art to have magnet 38 comprises [*sic*] an

annular disc and the trocar cap 24 having a lumen 32 and a funnel-shaped 30 [sic] disposed therein" falls woefully short of the type of explanation required by *Hong*.

Moreover, even if Uecker would have been instructive of anything to one of ordinary skill in "the surgical art," it still would not have suggested the combination recited in the previous version of claim 1. Starting with Lerman, it appears from the office action that Lerman's insert 40 supposedly corresponds to claim 1's trocar, and has a stem portion 42, which supposedly corresponds to claim 1's trocar cannula¹, and a rim 44, which supposedly corresponds to claim 1's trocar base. Lerman's stopper 80 supposedly corresponds to claim 1's trocar cap.

Uecker's dry well includes a tube 12 that goes through an enclosure or vessel 10, such as a nuclear reactor. A ball valve 18 attached to this tube outside the wall of the reactor vessel 10 includes a lower block 16 welded to the top of the tube, an upper block 24, and a retaining nut 26 that secures the upper block on top of the lower block. An annular magnet 38 surrounding an upward extending neck on the upper block maintains a ball 36 in a conical chamber 30 inside the upper block in place covering an opening in the upper block. An instrument probe 40 can be inserted through the neck in the upper block and into the interior of the reactor vessel through the tube extending through the vessel wall. The probe displaces the ball away from the opening in the conical chamber as it passes through the tube into the reactor.

Contrasting that with the applicant's claim 1, Uecker's annular magnet 36 does not secure anything like a trocar cap (claim 1)/stopper (Lerman) to a trocar base (claim 1)/rim

1. Claim 1's trocar cannula extends "through a tissue boundary" with "a distal end for placement on one side of the tissue boundary and a proximal end for placement on another side of the tissue boundary." Lerman's stem portion 42 does not have ends on either side of a tissue boundary. *See Fig. 2.*

of a continent ileostomy or colostomy insert (Lerman). Nor does the examiner contend as much. The office action simply asserts, without explanation, that Uecker's annular magnet 36, which forms part of a valve mechanism, would have suggested using an annular disc magnet in place of the discrete magnets 52 securing Lerman's stopper 80 to its insert 40. Neither reference gives any reason for making such a change. *See also KSR Int'l Inc. v. Teleflex, Inc.*, 350 U.S. 398 (2007) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness," quoting *Kahn, supra*.)

Besides the non-obviousness of the combination put forward by the examiner in the office action, claim 1 now recites that the trocar cap and trocar base include cooperating camming members for generating a force tending to separate the cap and the base upon movement of the cap transversely to the base. The office action does not address this feature of the applicant's invention, nor is there any possible reading of Lerman and Uecker that would have suggested it.

As for claim 12, it adds that at least one of a cap valve member includes a compliant toroidal body disposed in the cap and a trocar valve member including a compliant toroidal body disposed in the trocar base, wherein the toroidal body has a central opening and is disposed for compression axially when the cap is magnetically secured to the base thereby closing the central opening when a surgical instrument is not present in the lumen. The office action also does not address this feature of the applicant's invention, and no possible reading of Lerman and Uecker would have suggested it.

Claims 14 and 36

These claims are directed to a trocar without a trocar cap. Claims 14 and 36 both recite a trocar including an elongated cannula for extending through a tissue boundary and having a trocar base disposed at a proximal end of the cannula. The trocar further includes a magnet in the base surrounding a trocar lumen creating a magnetic field generally axially aligned with said lumen and having a predetermined strength for holding a distal end of an elongated surgical instrument in place in alignment with the lumen. Claim 14's magnet is an "annular disc"; claim 36's magnet is an "annular member."

The same points discussed above in connection with claims 1 and 12 as to the non-obviousness of using any teaching in Uecker to modify Lerman apply equally to claims 14 and 36. Nor is there any teaching in either Lerman or Uecker regarding creating a magnetic field axially aligned with a "lumen" through Lerman's continent ileostomy or colostomy or through Uecker's upper block, lower block, and retaining nut. As for Lerman, there is no discussion regarding choosing the strengths and placements of the discrete magnets to create a magnetic field axially aligned with the passageway 14 through the insert 40. In Uecker, the drawings show the annular magnet 38 and the probe 40 (see Fig. 2) slightly offset radially from the axis of the neck of the upper block.

The closest the office action comes to discussing this feature of the invention is to say that Lerman's "magnet 52 in said base is capable of having a predetermined strength for holding a distal end of an elongated surgical instrument in place in alignment with the lumen 46." But the applicant's claims say that the magnetic field actually has "a predetermined strength for holding a distal end of an elongated surgical instrument in place in alignment with said lumen." That the examiner might think Lerman's discrete

magnets are "capable of" creating such a magnetic field would not have made it obvious to actually provide one.

Claims 16 and 37

These claims depend from claims 14 and 36, respectively. They recite that the trocar base lumen "forms a funnel-shaped opening at said base that narrows along said lumen in a direction away from said proximal end of said base." The examiner equated the applicant's claimed funnel-shaped opening with Uecker's conical chamber 30.

Of course, for all of the reasons already discussed the applicant rejects any assertion that Uecker would have taught one of ordinary skill in the art anything concerning how to construct a trocar like that claimed by the applicant. Nevertheless, Uecker's conical chamber does not broaden in the same direction as the applicant's claimed funnel-shaped opening. An important purpose of the applicant's funnel-shaped opening is to help guide into the lumen the elongated surgical instrument that is axially aligned with the lumen by the magnetic field of base claims 14 and 36. Uecker's conical chamber 30 not only narrows in the wrong direction to perform such a guiding function, but its placement inside the body of the valve 18 makes it incapable of performing any guiding function at all.

Summary

Not only does Uecker fail the analogous-art test that it be either (1) in the field of the applicant's endeavor or (2) reasonably pertinent to the problem with which the inventor was concerned, but there is also no combination of Lerman and Uecker that teaches or suggests each and every feature of the applicant's claims. That failure is fatal to the examiner's obviousness rejection under 35 U.S.C. § 103.

M.P.E.P. § 2143.03 requires the “consideration” of every claim feature in an obviousness determination. To render a claim unpatentable, however, the examiner must do more than merely “consider” each and every claim feature; the asserted combination of the references must also teach or suggest each and every claim feature. *See In re Royka*, 490 F.2d 981 (CCPA 1974) (to establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art). Indeed, as the Board of Patent Appeals and Interferences has recently confirmed, a proper obviousness determination requires that the examiner make “a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.” *See In re Wada and Murphy*, Appeal 2007-3733, January 14, 2008 (copy attached), *citing In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis in original). Further, it is axiomatic that an asserted combination of references can render a claim unpatentable only if it at least includes all claim features. The Supreme Court has long held that obviousness is a question of law based on underlying factual inquiries, including ascertaining the differences between the claimed invention and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). Indeed, that is why M.P.E.P. § 904 instructs an examiner to conduct a prior art search that covers “the invention *as described and claimed*.” (emphasis added).

In sum, it remains well-settled that obviousness requires the examiner to show at least a suggestion of all of the features in a claim. *See In re Wada and Murphy, supra* (*citing CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) and *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). The examiner here has made no such showing, and the present application must accordingly be allowed.

ENTRY OF PRESENT AMENDMENT

The applicant is clearly entitled to entry of the changes to claims 1, 10, 12, and 36.

Amended claim 1 is, in essence, cancelled claim 9 rewritten in independent form. The changes to dependent claim 10 provide consistency with its amended base claim 1. New independent claim 12 is previous dependent claim 12 rewritten in independent form. And amended claim 36 is, in essence, canceled claim 40 rewritten in independent form. The positive recitation of the magnetic field in claims 14 and 36 is taken from existing dependent claim 5 (albeit in a somewhat different context).

Only the amendments to claims 16 and 37 present an issue as to their entry. The applicant respectfully submits that entry of the similar change to both of these claims, to recite the orientation of the claimed funnel-shaped opening, is proper because the piecemeal examination of the present application has resulted in those claims being treated on the merits for the first time in the pending office action.

The first office action, dated September 25, 2009, included an election of species requirement in which the embodiment of Figs. 1-3 of the present application was deemed separately patentable from the embodiment of Figs. 4 and 5. In the next office action, dated November 20, 2009, the examiner rejected the applicant's claims over Lerman, which discloses an arrangement with discrete magnets like that in the applicant's Fig. 4.

The next office action, dated March 3, 2010, was made final and rejected claims 1-14, 16, and 36-46 under 35 U.S.C. § 103 as unpatentable over Lerman in view of newly cited U.S. Patent 7,546,855 to Rodewald. The examiner asserted that Rodewald disclosed a funnel-shaped opening, but failed to account for the fact that Rodewald is not prior art to

the present invention because its effective filing date is after the filing dates of the applicant's provisional priority applications.

The examiner has agreed that Rodewald is not prior art to the present invention. However, the present office action was made final and again repeats the rejection in the immediately preceding office action, this time citing Lerman and Uecker. The citation of Uecker is thus the first time the examiner has asserted any prior art said to relate to the applicant's claims directed to a funnel-shaped opening in the trocar base.²

Thus, there has been no occasion before the present amendment to alter the wording of claims 16 and 37 to clarify the orientation of the applicant's funnel-shaped opening in the trocar base, because they were never rejected on prior art before now. Accordingly, entry of those claim changes is proper.

DRAWING CHANGE

Regarding a matter now being raised for the third time, the Amendment dated October 8, 2009, included a Submission of Drawing Change with a replacement sheet seven of the drawings that included a minor change in Fig. 8. The Amendment of December 2, 2009, requested that the next office action in the present application indicate that replacement sheet seven has been entered into the application. The office actions dated March 3 and March 30, 2010, both failed to act on the requested drawing change. The applicant again requests that the examiner approve the requested drawing change.

2. On top of the examiner's piecemeal approach to prosecution of the present application, the same examiner issued a Written Opinion, dated September 27, 2005, in corresponding PCT application no. PCT/US04/37502, finding that original claims 1-35 satisfied novelty and inventive step requirements. The Written Opinion did not cite the by then long-issued Lerman or Uecker patents. Accordingly, the present office action continues the incomplete and contradictory treatment given to this case every time this examiner has picked it up, beginning with the original PCT application.

CONCLUSION

The applicant believes that claims 1-8, 10-14, 16, 36-39, and 41-46 are patentable and respectfully requests that the present application be allowed.

Any fee associated with this paper should be charged to Deposit Account No. 50-0409.

Respectfully submitted,

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